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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CDx DIAGNOSTICS, INC., et al.,

Plaintiffs,

v.

HISTOLOGICS, LLC, et al.,

Defendants.

AND RELATED COUNTERCLAIMS.

Case No. 2:13-cv-7909-DOC-RNB

DEFENDANT HISTOLOGICS,
LLC'S MEMORANDUM OF
POINTS & AUTHORITIES IN
OPPOSITION TO PLAINTIFF'S
MOTION TO DISMISS
INVALIDITY, INEQUITABLE
CONDUCT,
UNENFORCEABILITY AND
FRAUD AFFIRMATIVE
DEFENSES AND
COUNTERCLAIMS

Date: April 21, 2014
Time: 8:30 a.m.
Room: 9D

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MEMORANDUM OF POINTS AND AUTHORITIES

Defendant and counterclaimant Histologics, LLC (“Histologics”) hereby submits its Opposition to plaintiffs and counter-defendants CDx Diagnostics, Inc. (“CDX”) and Shared Medical Resources, Inc.’s (“SMR”) (collectively “Plaintiffs”) Motion to Dismiss Invalidity, Inequitable Conduct, Unenforceability, and Fraud Affirmative Defenses and Counterclaims (“Motion”) (Dkt. No. 119).

I. Introduction

Plaintiffs propose to seek judgment on the pleadings of Histologics’s affirmative defenses and counterclaims for invalidity, inequitable conduct, unenforceability, and fraud in the procurement of U.S. Patent No. 6,258,044 (“the ’044 patent”). More particularly, Plaintiffs urge the Court to apply the equitable doctrine of assignor estoppel as an automatic bar to any validity or enforceability challenge of the Lonky ’044 patent without any analysis of the facts or balancing the equities. Plaintiffs’ motion should be denied because (i) it is a premature motion for summary judgment guised as a Rule 12(c) motion, (ii) the equities weigh in favor of denying application of the assignor estoppel doctrine, and (iii) the doctrine does not even apply to Defendants Poplar Healthcare PLLC or Mattison Pathology LLP, and therefore if the patent is invalid for one it is invalid for all.

First, Plaintiffs’ Rule 12 motion relies on facts outside of the pleadings and must be converted to a Rule 56 motion for summary judgment. However, the Court established a discovery cut off date of February 20, 2015 and a motion cut-off date for hearing dispositive motions of March 9, 2015. (*See* Dkt. No. 101, Sched. Order, at 1.) The Court also informed counsel at the Scheduling Conference that it would take up these types of motions all at once at the March 9, 2015 hearing, not on a piece meal basis as Plaintiffs seek in this premature motion. Even if this premature and factually complex motion were decided now, genuine issues of material fact exist that preclude summary judgment at this early stage of the proceedings, prior to any discovery being conducted.

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Second, the vitality of the assignor estoppel doctrine is seriously in doubt given Supreme Court case law.¹ Even if the doctrine remains viable, Plaintiffs ignore the very case law they rely upon, and urge the Court to improperly apply the equitable doctrine of assignor estoppel automatically without consideration or balancing of the equities. Plaintiffs incorrectly represent material facts and ignore others that compel balancing the equities *against* applying assignor estoppel even if the Court were to reach this issue before the date for dispositive motions later in the case.

Lastly, there are other defendants that assert this same defense and addressing this motion now would not advance case preparation. Specifically, co-defendants Poplar Healthcare PLLC (“Poplar”) and Mattison Pathology LLP (“Mattison”) assert that the ’044 patent is invalid and unenforceable. These co-defendants are not in privity with the purported inventor of the asserted patent and assignor estoppel will not apply to them. *See Checkpoint Sys., Inc. v. All-Tag Sec. S.A.*, 315 F. Supp. 2d 660 (E.D. Penn. 2004) (customer was not estopped by the doctrine of assignor estoppel from attacking validity of the patent).

II. Background and Facts

A. Defendant Histologics and Its Accused Products

Plaintiffs accuse Histologics’s Soft-ECC[®] and SoftBiopsy[®] products of infringing the ’044 patent. These products represent the latest advancement in devices used in the field of minimally invasive biopsies. Histologics was

¹ “The federal cases, decided either shortly before *Lear* or since then, that discuss the doctrine of assignor estoppel reveal some uncertainty about the continued vitality of the doctrine.” *Diamond Scientific v. Ambico, Inc.*, 848 F.2d 1220, 1223 (Fed. Cir. 1988) (“[The *Lear* opinion] reviewed the history of ‘patent estoppel’ in general, and indicated that the Court’s previous decisions had sapped much of the vitality, if not the logic, from the assignment doctrine as well.”) (citing *Lear, Inc. v. Adkins*, 395 U.S. 653, 89 S.Ct. 1902 (1969)).

1 established in 2008 to improve women's healthcare and to advance the tools and
2 methods of histologic sampling for abnormal cervical cancer screening. Such
3 screenings are an important step in early detection of diseases such as cervical
4 cancer in women and save lives. The Soft-ECC[®] and SoftBiopsy[®] devices are the
5 most recent inventions of Dr. Neal Lonky, who has been developing biopsy tools as
6 far back as the late 1980s and early 1990s.

7 The Soft-ECC[®] device is an endocervical curette used to collect trans-
8 epithelial cell samples from endocervix tissue during a gynecological examination.
9 (*See* Korrell Decl., Exh. A.) The minimally invasive design of the Soft-ECC[®]
10 device employs KYLON[®] fabric at the tip, which contains a plurality of
11 individually-arranged hooks that abrade the tissue with friction and collect the
12 specimen within the rows of the hook-shaped bristles. (*See id.*)

13 The Soft-Biopsy[®] device is used to collect trans-epithelial histology cell
14 samples from the exocervix or lower genital tract tissue during a gynecological
15 examination. (*See* Korrell Decl., Exh. B.) Like the Soft-ECC[®] device, Soft-
16 Biopsy[®] device employs KYLON[®] fabric at the tip which is used to abrade the
17 tissue with friction and collect the specimen within the rows of the hook-shaped
18 bristles. (*See id.*)

19 Over the past several years, Histologics has conducted clinical trials that have
20 shown that these devices are as effective as conventional devices in collecting
21 trans-epithelial tissue cells, but are far more gentle. (*See* Berger Decl., Exh. 6.)

22 **B. Dr. Neal Lonky's Development of the SpiraBrush CX**

23
24 Beginning in 1991, Dr. Neal Lonky brought the SpiraBrush CX invention to
25 Trylon Corporation for the purposes of developing and commercializing it for use
26 by doctors to take cell samples of epithelial tissue by physicians conducting
27 gynecological examinations. (Neal Lonky Decl., at para. 2-3.) As part of the
28 development, Trylon engaged brush manufacturers and negotiated supply

1 agreements, tested product samples, organized clinical studies, and applied to the
2 FDA for certifications. (Martin Lonky Decl., at para. 4.)

3 As part of Trylon's efforts to develop and commercialize the product, a
4 federal trademark application for the name "SpiraBrush CX" was filed with the
5 U.S. Patent and Trademark Office ("USPTO"). (Martin Lonky Decl., at para. 5.)
6 The USPTO indicates that the trademark application was filed on March 22, 1993,
7 with a first use in commerce on December 4, 1992. (*Id.*) Also, as part of the
8 trademark registration application process, samples of the SpiraBrush CX product
9 were submitted to the USPTO on March 18, 1993 as evidence of use of the
10 trademark in commerce. (*Id.*)

11 Based on the financial records of Trylon, the sales of the SpiraBrush CX
12 amounted to approximately \$1 million up to and including June 30, 1994. (Martin
13 Lonky Decl., at para. 6.)

14 In early 1998, Trylon considered filing for a patent on the SpiraBrush
15 product and engaged the Lyon & Lyon LLP law firm to explore that possibility.
16 (Martin Lonky Decl., at para. 7.) Lyon & Lyon attorney Sokol prepared and sent
17 several drafts of a patent applications to Trylon—one on April 15, 1998 and one on
18 June 8, 1998. (*Id.*) In addition to preparing patent application drafts, Lyon & Lyon
19 conducted a prior art search for other brushes that had been patented. (*Id.*) Based
20 on this search, and because Trylon had been marketing and selling the SpiraBrush
21 for more than five years, Trylon decided that it would not pursue a patent on the
22 device and abandoned the effort. (*Id.*)

23 **C. OralScan's Attempts To Patent the SpiraBrush Product For Use** 24 **In the Oral Cavity**

25 In June of 1998, Trylon was approached by Mark Rutenberg of OralScan
26 Laboratories, Inc. ("OralScan") seeking to use the SpiraBrush CX product for oral
27 examinations. (Martin Lonky Decl., at para. 8.) In July of 1998, Martin Lonky,
28

1 CEO of Trylon, entered into a joint venture agreement with OralScan permitting
2 OralScan's exclusive use of the SpiraBrush product for oral examinations. (Martin
3 Lonky Decl., at para. 9.) As part of the joint venture agreement, Dr. Neal Lonky
4 signed an assignment which conveyed to OralScan exclusive rights to use and sell
5 the SpiraBrush for use in the oral cavity. (*See* Berger Decl., Exh. 3.) At Mr.
6 Rutenberg's request, the agreement also included an assignment to OralScan of any
7 patents that OralScan obtained covering the SpiraBrush—this was despite Trylon's
8 warnings to OralScan of the patentability issues that such a patent would face.
9 (Martin Lonky Decl., at para. 10.)

10 On July 23, 1998, OralScan's patent lawyer, Peter Berger, filed a provisional
11 patent application (the "'910 provisional application"). (*See* Korrell Decl., Exh. C.)
12 On July 23, 1999, OralScan's patent lawyer, Peter Berger, submitted a non-
13 provisional patent application (the "'425 application") to the USPTO, claiming
14 priority to the '910 provisional application and naming Dr. Neal Lonky as one of
15 the two co-inventors. (*See* Korrell Decl., Exh. D.) Dr. Neal Lonky never met or
16 worked with the named co-inventor, Jeremy James Michael Papadopoulos, nor did
17 he participate in any review or preparation of the '910 provisional or subsequent
18 non-provisional application. (Neal Lonky Decl., at para. 9.) Also included in this
19 filing was a declaration of inventorship and an assignment of power of attorney that
20 include signatures purporting to be that of Dr. Neal Lonky. (*See* Berger Decl., Exh.
21 3.) Dr. Neal Lonky did not, however, sign the declaration of inventorship or power
22 of attorney. (Neal Lonky Decl., at para. 10.) He did not authorize anyone to sign on
23 his behalf. (*Id.*)

24 **D. Ownership of the '044 Patent**

25
26 In January 2001, OralScan assigned the '425 patent application to Trylon.
27 (*See* Korrell Decl., Exh. E.) This assignment identifies the '425 patent application
28 and was a part of the second Trylon/OralScan joint venture agreement, signed by

1 the parties in December 2000. (*See* Korrell Decl., Exh. F.) In June of 2001 Dr.
2 Neal Lonky signed an assignment conveying the '425 patent application to the
3 Trylon/OralScan Company joint venture. (*See* Berger Decl., Exh. 3.)

4 As a condition to a loan agreement with Pacific Republic Capital, LLC
5 ("PRC"), dated November 12, 2003, Trylon pledged its assets as collateral, which
6 included its ownership interest in the Trylon/OralScan joint venture. (*See* Korrell
7 Decl., Exh. G.) When Trylon later defaulted on this loan, certain assets of Trylon's
8 were acquired by Shared Medical Resources. (*See* Korrell Decl., Exh. H.) Trylon
9 never sold or assigned the '044 patent. (Martin Lonky Decl., at para. 13.) The
10 patent belonged to the Trylon/OralScan joint venture, not Trylon. (*See* Korrell
11 Decl., Exh. F.)

12 On March 8, 2006, there was a purported assignment between Trylon and
13 OralScan. (*See* Korrell Decl., Exh. I.) In this assignment, Gordon M. Olson asserts
14 that, "pursuant to the loan security agreement, [Gordon's company, Shared Medical
15 Resources] has a power of attorney from [Trylon] to execute this assignment of the
16 patent." (*Id.*)

17 On April 17, 2006 OralScan and Shared Medical Resources entered into a
18 "clarification agreement," unilaterally claiming to void the assignment Dr. Neal
19 Lonky signed in June 2001. (*See* Korrell Decl., Exh. J.)

20 Trylon never filed for bankruptcy. (Martin Lonky Decl., at para. 15.)

21 **E. OralScan's Shadow Patent Application**

22
23 On February 23, 1999, OralScan's patent lawyer filed a provisional patent
24 application. (U.S. Application Ser. No. 60/121,255 (the "'255 provisional".) On
25 April 23, 1999, OralScan's patent lawyer filed a non-provisional patent application,
26 claiming priority to the '255 provisional, and naming Dore Eisen, Stephen Frist,
27 and Joel Recht as inventors. (*See* Korrell Decl., Exh. K (the "'219 application").)
28 The application does not name Dr. Neal Lonky as an inventor. On October 2, 2001,

1 the USPTO issued U.S. Patent No. 6,297,044 from the '219 application. (*See*
2 Korrell Decl., Exh. L (the "'219 application").)

3
4 **III. Plaintiffs' Rule 12(c) Motion to Dismiss is Not Proper And Should Be Denied On Procedural Grounds.**

5 Plaintiffs' Motion should be denied on procedural grounds. The Motion is
6 an improper attack on the pleadings before the pleadings have closed. Specifically,
7 a Rule 12(c) motion is reserved for when the pleadings have closed, which has not
8 yet occurred. Plaintiffs failed to timely file a responsive pleading to Histologics'
9 counterclaims and affirmative defenses and have therefore waived making such
10 defenses. Moreover, Plaintiffs' Motion is based significantly on evidence outside
11 of the pleadings, requiring it to be treated as a motion for summary judgment,
12 which is premature at this early stage in the litigation.

13
14 **A. Plaintiff's Motion is Not A Substitute for An Answer to Histologics's Counterclaims To Which CDx and SMR Are In Default.**

15
16 On February 28, 2014, Histologics filed an Amended Answer to Plaintiffs'
17 complaint (Dkt. No. 109). Histologics pleaded counterclaims and affirmative
18 defenses of invalidity, inequitable conduct, unenforceability, and fraud in the
19 procurement of the '044 patent. Plaintiffs' time to respond to Histologics'
20 Amended Answer and Counterclaims passed on March 24, 2014. *See* FED. R. CIV.
21 PROC. 12(a)(1)(B) and 6(d) (requiring a party to serve an answer to a counterclaim
22 or cross claim within 21 days after service, plus three days for electronic service).
23 Plaintiffs are in default and their motion is premature because motions under Rule
24 12(c) are permissible only after the pleadings have closed. *See* FED. R. CIV. PROC.
25 12(c) ("After the pleadings are closed—but early enough not to delay trial—a party
26 may move for judgment on the pleadings.").

B. Plaintiffs' Motion is Improper for Introducing Evidence Outside of the Pleadings.

In ruling on a 12(c) motion, the Court may consider the pleaded allegations, exhibits, attached to the complaint, and matters of public record. *See Grajales v. Puerto Rico Ports Auth.*, 682 F.3d 40, 44-45 (1st Cir. 2012); *Barany-Snyder v. Weiner*, 539 F.3d 327, 332 (6th Cir. 2008). If the court, in its discretion, considers (or does not exclude) extrinsic evidence presented on a Rule 12(c) motion, the court must convert the motion into a request for summary judgment under Rule 56. *See* FED. R. CIV. PROC. 12(d) ("If, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56."). Plaintiffs' Motion should not be treated as a motion for summary judgment because discovery has not begun and legal issues such as assignor estoppel and inequitable conduct rely heavily on extrinsic factual material. *See id.* (the rule continues: "All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion.").

Moreover, at this early stage, a Rule 56 motion is premature. The Court set a discovery cutoff of February 20, 2015 and a motion cutoff for hearing dispositive motions on March 9, 2015. (Dkt. No. 101, Sched. Order, at 1.) The Court made clear at the February 3, 2014, Scheduling Conference that it would take up these types of dispositive motions at once at the March 9, 2015, hearing, not piece meal as Plaintiffs seek here.

Plaintiffs submitted declarations and attached numerous exhibits, several of questionable origins and authenticity. Histologics has not had an opportunity to depose Plaintiffs' declarants, nor has Histologics received any discovery, although requests were served several months ago. For each of these reasons, Plaintiffs' motion is premature and should be denied.

1 **IV. Assignor Estoppel Is Not an Automatic Bar to Any Validity and**
2 **Enforceability Challenge; It Requires A Balancing of the Equities.**

3 Plaintiffs assert assignor estoppel as if it were an automatic bar of any
4 challenge to the validity and enforceability of the Lonky '044 patent. This is not
5 the law. *Diamond Scientific*, which Plaintiffs rely on, and other Federal Circuit
6 case law on assignor estoppel require the Court to analyze the facts of each case and
7 balance the equities to determine whether assignor estoppel should be applied in a
8 given case. This balancing is particularly important where the reasons for the
9 patent's invalidity are due to no fault attributable to the purported assignor, here,
10 Dr. Neal Lonky.

11 In *Diamond Scientific*, the Federal Circuit noted that "the doctrine of assignor
12 estoppel may no longer be a broad equitable device susceptible of automatic
13 application." *Diamond Scientific v. Ambico, Inc.*, 848 F.2d 1220, 1225-26 (Fed.
14 Cir. 1988). Instead, the court explained that the doctrine's application depends on
15 the balance of equities between the parties:

16 . . . we believe that the primary consideration in now
17 applying the doctrine is the measure of unfairness and
18 injustice that would be suffered by the assignee if the
19 assignor were allowed to raise defenses of patent
20 invalidity. Our analysis must be concerned mainly with
21 the balance of equities between the parties.

22 *Id.* At 1225.

23 *Diamond Scientific* is not unique in this respect. Since that case, the Federal
24 Circuit regularly has stated that the equities must be balanced to determine whether
25 to apply assignor estoppel. *See Q.G. Products, Inc. v. Shorty, Inc.*, 992 F.2d 1211,
26 1213 (Fed. Cir. 1993) ("In this case, this court first decides whether the district
27 court was correct to apply the doctrine of assignor estoppel. This determination
28 requires a balancing of the equities of the case."); *Carroll Touch, Inc. v. Electro*
Mechanical Systems, Inc., 15 F.3d 1573, 1579 (Fed. Cir. 1993) ("A determination
whether assignor estoppel applies in a particular case requires a balancing of the

1 equities between the parties.”) (citing *Diamond Scientific*). The determination is a
2 matter committed to the sound discretion of the trial court. *See Carroll Touch, Inc.*
3 15 F.3d at 1579.

4 The Federal Circuit has instructed that facts and circumstances may tip the
5 balance of the equities in the assignor’s favor. “It is true that in a proper case
6 general principles of equity may preclude use of assignor estoppel to bar a viable
7 equitable defense arising from post-assignment events.” *Shamrock Techs., Inc. v.*
8 *Medical Sterilization, Inc.*, 903 F. 2d 789, 795-96 (Fed. Cir. 1990) (citing
9 *Buckingham Prods. v. McAleer Mfg. Co.*, 108 F.2d 192 (6th Cir. 1939) (inequitable
10 conduct may defeat invocation of assignor estoppel because “one may not profit
11 from his own fraud”) and *Westinghouse Elec. & Mfg. Co. v. Formica Insulation*
12 *Co.*, 266 U.S. 342, 352-53, 45 S.Ct. 117, 120-21 (1924) (timing of assignment may
13 affect scope of resulting estoppel)).

14 Plaintiffs selectively cite favorable language from *Diamond Scientific* and
15 *Shamrock Techs.*, ignoring the weight of case law that requires a full analysis of *all*
16 relevant facts (see discussion below). Instead of automatically applying assignor
17 estoppel as Plaintiffs assert, the Court should look to the facts, particularly showing
18 that the patent is invalid due to no fault of the purported assignor and deny
19 application of the doctrine based on balancing the equities.

20
21 **A. The Equities Weigh Against Application of Assignor Estoppel.**

22 In deciding whether to apply assignor estoppel, the “analysis must be
23 concerned mainly with the balance of equities between the parties.” *Diamond*
24 *Scientific*, 848 F.2d at 1225. The Federal Circuit in *Diamond Scientific* relied on
25 two factors, the inventor’s oath and the consideration received for the assignment,
26 in deciding to apply assignor estoppel:

27 When the inventor-assignor has signed the Oath, Power of
28 Attorney and Petition, which attests to his belief in the
validity of the patents, and has assigned the patent rights
to another for valuable consideration, he should be

1 estopped from defending patent infringement claims by
2 proving that what he assigned was worthless.

3 *Id.* at 1226.

4 Neither of these factors exists in this case. First, there was no consideration
5 paid for the assignment of the asserted '044 patent. The purported assignment Dr.
6 Neal Lonky signed on July 12, 1998, was not for a patent, because none existed, but
7 for the SpiraBrush product that Dr. Neal Lonky developed years before. Dr. Neal
8 Lonky assigned to OralScan the exclusive right to use and sell the SpiraBrush
9 product in performing cell samples from the oral cavity and similar epithelium
10 tissue cells. (*See* Berger Decl., Exh. 3.) Any consideration that Dr. Neal Lonky
11 and/or his company received was not for the assignment of the patent, because none
12 existed, but for assigning rights to use and sell the SpiraBrush product exclusively
13 in a medical field. (*See id.*)

14 Furthermore, Dr. Neal Lonky did not sign anything asserting any belief in the
15 validity of the patent. Dr. Neal Lonky never saw the patent application and never
16 signed any declaration of inventorship, validity, or power of attorney. The
17 signatures in the patent application are not Dr. Neal Lonky's.²

18 Additional facts tilt the equities further against estopping Histologics from
19 asserting invalidity and inequitable conduct. These facts underscore that the
20 asserted patent is invalid and unenforceable due to no fault attributable to Dr. Neal
21 Lonky. Material factual questions remain about the extent of the fraud on the
22 USPTO by OralScan, the predecessor of Plaintiff CDx Diagnostics, and its patent
23 lawyers.

24 **1. The Evidence Shows That Dr. Neal Lonky Did Not Assign**
25 **Any Patent.**

26
27 ² It is unclear who signed Dr. Neal Lonky's name, but he did not sign any
28 documents that formed the application for the '044 patent. (*See* Neal Lonky Decl.,
at para. 10.)

1 Plaintiffs’ assertion that Dr. Neal Lonky, “[a]fter OralScan and Trylon
2 entered into their joint venture, . . . assigned the entire right, title and interest to the
3 claimed invention to OralScan in July, 1999” (Pls. Mem. at 5) is materially false.
4 Plaintiffs do not cite to any evidence dated July of 1999. (*See* Berger Decl., Exh.
5 3.) And, the documents they do cite do not show that Dr. Neal Lonky assigned all
6 rights to the invention as alleged in Plaintiffs’ Motion.

7 Dr. Neal Lonky never assigned the ’044 patent to OralScan. Rather, on July
8 12, 1998, Dr. Neal Lonky assigned to OralScan the right to use and sell the
9 SpiraBrush CX product exclusively in performing cell samples from the oral cavity
10 and similar epithelium tissue. (*See* Berger Decl., Exh. 3.) At the time Dr. Neal
11 Lonky signed this document, there was no patent or even a patent application for
12 Dr. Neal Lonky to assign. What Dr. Neal Lonky did assign was use of the
13 SpiraBrush CX product which Dr. Neal Lonky had been designing, testing,
14 marketing, and selling for over five years. At the time Dr. Neal Lonky made this
15 assignment, Trylon CEO Martin Lonky told OralScan of these disclosures and sales
16 and other reasons why the SpiraBrush product could not be protected by a valid
17 patent. Despite this, OralScan insisted upon this document also including a
18 provision where OralScan would be permitted to file a patent application to cover
19 use of the SpiraBrush in the oral cavity and similar epithelium only. (*See* Berger
20 Decl., Exh. 3.)

21 Plaintiffs’ Exhibit 3 is also inconsequential. Exhibit 3 includes a document
22 purporting to assign the ’425 patent application by Dr. Neal Lonky to “The
23 OralScan/Trylon Company” joint venture in June of 2001. (*See* Berger Decl., Exh.
24 3.) Plaintiffs fail to mention that they had previously gone out of their way to
25 disavow this agreement and unilaterally declare that the agreement was void. In a
26 purported “clarification agreement” made between Plaintiffs (and not Dr. Neal
27 Lonky), they agreed that “at the time the Lonky Assignment was purportedly made,
28 Neal M. Lonky had no rights in and to the Patents to convey, therefore the Lonky

1 Assignment was ineffective, and transferred and/or conveyed no rights.” (Korrell
2 Decl., Exh. J.) Plaintiffs time and again have attempted to change historical events
3 to best suit their positions at the moment. Such manipulations cannot be reconciled
4 with the truth, which is Dr. Neal Lonky did not assign the ’044 patent, and plaintiffs
5 have no documents to show that he did.

6 Plaintiffs’ selective recitation of facts also omits a 2001 assignment by
7 OralScan (Plaintiff CDx Diagnostics’ predecessor) to Trylon. (Korrell Decl., Exh.
8 E.) In this document, OralScan purports to be the owner of the ’425 patent
9 application and assigns it to Trylon. (*Id.*) This assignment was a part of a larger
10 joint venture agreement between OralScan and Trylon (the “2000 Agreement”)
11 where OralScan agreed to pay royalties to Trylon for OralScan’s continued
12 exclusive use of the SpiraBrush CX product at \$0.25 per brush in addition to unpaid
13 balance of royalties due for the prior two years (\$125,000 for 1999 and \$132,500
14 for 2000). (Korrell Decl., Exh. F.) Presumably, the existence of this assignment is
15 the reason for Plaintiffs’ disavowing (but now relying upon) Dr. Neal Lonky’s June
16 2001 assignment, but it begs the question as to whether Dr. Neal Lonky actually
17 ever did assign the ’044 patent.

18 Regardless, both purported assignments were made before the patent claims
19 had been granted and finalized by the USPTO, and a determination must be made
20 as to the scope of the assignment, if any. The Federal Circuit has instructed that
21 assignments of subject matter unbounded by finalized claims require more analysis
22 of the evidence to define the assignor’s representations:

23 Where a party assigns a patent, and the equities demand
24 application of estoppel, the analysis is straightforward.
25 The assignor implicitly attests to the value of the assigned
26 patent. The assignor’s representations cover no more nor
27 less than the assigned rights.

28 * * *

Where, however, a party assigns an “invention” or
application, and the equities advise application of
estoppel, the analysis is more elaborate. Unlike
assignment of a patent, a party’s representations upon
assignment of an application are not as clearly bounded.

1 *Q.G. Prods., Inc. v. Shorty, Inc.*, 992 F. 2d 1211, 1212-13 (Fed. Cir. 1993) (citing
2 *Westinghouse Elec. & Mfg. v. Formica Insulation Co.*, 266 U.S. 342, 351, 45 S.Ct.
3 117, 120 (1924)).

4 In both purported assignments, Dr. Neal Lonky conveys the right to use and
5 sell the SpiraBrush CX product for performing cell samples from the oral cavity
6 and similar epithelium tissue. By asserting in this case that Histologics'
7 gynecological devices infringe the '044 patent, Plaintiffs assert this patent far
8 beyond what was initially assigned. If Dr. Neal Lonky assigned anything relating
9 to the SpiraBrush product, it was limited to the oral cavity..

10
11 **2. Dr. Neal Lonky Did Not Sign or Authorize Lawyers To Sign
The Declaration and Power of Attorney.**

12 Plaintiffs' assertion that "Trylon submitted an inventor declaration bearing
13 Neal Lonky's signature, stating that he was an inventor of the claimed subject
14 matter and was unaware of anything that would prevent a patent from being
15 granted" (Pls. Mem. at 5) is materially false on two counts. First, Plaintiffs' Exhibit
16 8 is a declaration relating to small entity status, which further states that the things
17 asserted are true to the signor's knowledge or belief:

18 I hereby declare that all statements made herein of my
19 own knowledge are true and that all statements made on
information and belief are believed to be true

20 (See Berger Decl., Exh. 8.) There is no declaration in Exhibit 8 denying any
21 awareness of information that would prevent the patent from being granted.
22 Plaintiffs' description of this document is misleading at best.

23 Second, the signature that Plaintiffs state belongs to Neal Lonky is not his.
24 Dr. Neal Lonky never reviewed the '425 patent application (which later matured
25 into the '044 patent), nor the earlier-filed provisional patent application to which
26 the '425 patent application claims priority. (Neal Lonky Decl., at para. 10.) Dr.
27 Neal Lonky recently reviewed the Declaration and Power of Attorney and he
28

1 confirmed that the signatures alleged to be his are not his. (*Id.*) Reviewing the
2 signatures in other documents Plaintiffs cited reveals distinct differences between
3 the signatures. (*Compare, e.g.,* Berger Decl., Exh. 3 (two examples of Dr. Neal
4 Lonky’s signature) *with* Berger Decl., Exh. 8 (not Dr. Lonky’s signature).) Further,
5 Dr. Neal Lonky did not authorize anyone to sign his name. (Neal Lonky Decl., at
6 para. 10.)

7 Therefore, unlike in *Diamond Scientific*, the inventor declaration that Dr.
8 Neal Lonky purportedly signed in the ’940 patent application includes no
9 statements as to the validity of the patent and should not weigh in favor of applying
10 the doctrine. One of the two facts that compelled the court in *Diamond Scientific* to
11 apply assignor estoppel was the content of the inventor’s oath submitted to the
12 USPTO during the prosecution of the patent-at-issue. *See* 848 F.2d at 1225. That
13 oath included a statement that the “invention was never known or used before his
14 invention and that is was not previously patented or described in any publication in
15 any country.” *Id.* The Federal Circuit noted that “the inventor-assignor has signed
16 the Oath, Power of Attorney and Petition, which attests to his belief in the validity
17 of the patents.” *Id.* at 1226. Even assuming that Dr. Neal Lonky did sign the
18 Declaration, which he denies, the document makes no statements about the
19 patentability of the invention disclosed. Whether Dr. Neal Lonky signed the
20 inventor declaration or not, the key language that compelled the court in *Diamond*
21 *Scientific* to apply assignor estoppel is absent here, and weighs ***against*** application
22 of the doctrine.

23
24 **3. Plaintiffs Incorrectly Characterize Payments Made to
Trylon as Consideration for a Patent Assignment.**

25 Plaintiffs assert Trylon received “about \$200,000” in license fees from
26 OralScan “during Trylon’s ownership of the ’044 patent.” (Pls. Mem. at 3.) This is
27 a gross mischaracterization. OralScan’s royalty payments owed to Trylon began to
28

1 accrue well before any patent rights existed. (See Korrell Decl., Exh. F, at ¶4.2 (the
2 “2000 Agreement”).) In the 2000 Agreement, OralScan agreed to pay Trylon
3 \$125,000 for its sales and use of the SpiraBrush CX in 1999 and \$132,500 in 2000.
4 (*Id.*) The ’044 patent did not issue from the USPTO until months later in July of
5 2001. Consequently, no patent royalties could have even accrued before then.

6 These payments were not patent royalties as Plaintiffs suggest, they were for
7 the right to use the SpiraBrush CX product, which had been publicly known and
8 unpatented for years. (Martin Lonky Decl., at para. 12.) OralScan first made the
9 agreement to pay Trylon before any patent application was filed with the USPTO.
10 (*See id.*) The agreement between Trylon and OralScan was for OralScan to use and
11 sell the SpiraBrush CX for oral examinations, without regard to any patent rights,
12 and therefore, neither Trylon or Dr. Lonky received consideration for patent rights
13 and this fact also weighs *against* application of the doctrine.

14
15 **4. The Fraud OralScan Committed on the USPTO Works In**
16 **Favor of Histologics Presenting Evidence Of Invalidity and**
Unenforceability of the ’044 Patent .

17 Plaintiffs' and its predecessor OralScan's conduct also *weighs* against
18 application of the assignor estoppel doctrine. A patent statutorily is barred under 35
19 U.S.C. § 102(b) if its subject matter was in public use or on sale more than one year
20 before the earliest filing date of the patent. The ’044 patent claims priority to a
21 provisional application filed on July 23, 1998. Therefore any sales or public uses of
22 the patented technology prior to July 23, 1997 would invalidate the patent.

23 OralScan was aware of the products Dr. Neal Lonky developed and sold
24 beginning in 1992, seven years before OralScan’s patent lawyer, Peter Berger, filed
25 the ’425 patent application for the SpiraBrush product. When OralScan expressed
26 interest in filing a patent application for the SpiraBrush product, Trylon CEO
27 Martin Lonky disclosed that the SpiraBrush CX had been publicly known and on
28 sale for the past six or seven years. (Martin Lonky Decl., at para. 10.) Trylon also

1 disclosed to OralScan material prior art that Trylon obtained during its own
2 investigation of filing a patent application. (*Id.*) Despite this information,
3 OralScan had its patent lawyer pursue a patent and did so without informing the
4 USPTO of the material prior art which raised questions of validity. As the Federal
5 Circuit has stated often, OralScan and its lawyer cannot claim ignorance to these
6 facts:

7 [O]ne should not be able to cultivate ignorance, or
8 disregard numerous warnings that material information or
9 prior art may exist, merely to avoid actual knowledge of
10 that information or prior art. Where one does, deceptive
11 intent may be inferred. Once an attorney, or an applicant,
12 has notice that information exists that appears material
13 and questionable, that person cannot ignore that notice in
an effort to avoid his or her duty to disclose.
Similarly, . . . absent credible evidence of good faith,
evidence of a knowing failure to disclose sales that bear
all the earmarks of commercialization reasonably supports
an inference that the inventor's attorney intended to
mislead the PTO.

14 *Brasseler, USA I, LP, v. Stryker Sales Corp.*, 267 F. 3d 1370, 1383 (Fed. Cir. 2001)
15 (internal quotes and cites omitted) (*quoting FMC Corp. v. Hennessy Industries,*
16 *Inc.*, 836 F. 2d 521, 526 n.6 (Fed. Cir. 1988) and *Paragon Podiatry Lab., Inc. v.*
17 *KLM Labs., Inc.*, 984 F.2d 1182, 1193 (Fed.Cir.1993)).

18 Because OralScan and its lawyer did not disclose to the USPTO the
19 information about the years of public use and sales³ of the SpiraBrush CX and the
20 material prior art that Trylon gave OralScan, the '044 patent issued without full
21 disclosure to the patent examiner. Not only is this in violation of the USPTO's rule
22 for applicants to disclose information material to patentability (*see* 37 C.F.R. 1.56),
23 the claims are written in a way that seeks to remove from the public domain what
24 had been previously there. In order to prevent OralScan, and its successor CDx,
25 from benefiting from intentionally withholding prior sales, public use, and prior art
26

27 ³ One notable evidence of use is Trylon's registered trademark of SpiraBrush CX,
28 the application for which was filed in 1993, documenting first use of the product in
commerce in 1992.

1 from the Patent Office, Histologics should not be barred from showing OralScan's
2 misconduct. "[I]nequitable conduct [on the part of the assignee] should defeat its
3 right to invoke the rule of [assignor] estoppel." *Buckingham Products Co. v.*
4 *McAleer Mfg. Co.*, 108 F. 2d 192, 195 (6th Cir. 1939).

5 Further evidence of OralScan's and its lawyer's inequitable conduct is shown
6 by filing a separate patent application with claims that are the same in scope as the
7 Lonky '044 patent.⁴ This "shadow patent application" was prosecuted by OralScan
8 and its patent lawyer in parallel with the Lonky '425 patent application, but the
9 existence of the other application was never disclosed to the USPTO. More
10 importantly, OralScan and its patent lawyer caused this shadow patent application
11 to issue as a separate patent, U.S. Patent No. 6,297,044 (the "Eisen patent"),
12 without naming Dr. Neal Lonky as an inventor. This was entirely improper and yet
13 another among OralScan and its lawyer's acts of deceit in connection with these
14 inventions.

15 Further, some of the material prior art that was cited by the patent examiner
16 in the Eisen shadow patent application was never disclosed by OralScan and its
17 lawyer in the Lonky '425 patent application. In addition, the specification of the
18 Eisen patent references the SpiraBrush CX by name, indicating that OralScan and
19 its lawyer believed that the Eisen patent and the SpiraBrush CX were in the same
20 field of use. Given the similarity between the two applications and the materiality
21 one examiner found in certain prior art references, OralScan and its lawyer's
22 decision to withhold such information from the patent examiner reviewing the '425
23 application can only be seen as intentionally deceitful. In sum, plaintiff CDx's (and
24 its predecessor, OralScan) inequitable conduct weighs *against* application of the
25 doctrine.

26
27
28 ⁴ As further evidence of their similarity, it can be seen that Figs. 1, 2, and 3 of the
Lonky '044 patent and Figs. 6, 7, and 8 of the Eisen patent are identical.

1 **5. Plaintiffs’ Post-Assignment Attempts to Enforce the ’044**
2 **Patent Against Devices Used in Examinations Other than the**
3 **Oral Cavity Militates Against Estopping Histologics from**
4 **Challenging its Validity.**

5 Lastly, Plaintiffs recent conduct also tips the scale in favor of denying
6 application of the doctrine. Plaintiffs now claim to own a ground-breaking,
7 foundational patent that excludes the world from making or selling any device that
8 samples any epithelium. Because Dr. Neal Lonky invented, manufactured,
9 marketed, and sold the SpiraBrush as early as 1992, it is implausible that such a
10 broad interpretation of the patent could have ever been possible.

11 As the Federal Circuit noted in *Shamrock Techs.*, “general principles of
12 equity may preclude use of assignor estoppel to bar a viable equitable defense
13 arising from post-assignment events.” 903 F.2d at 795-796. Plaintiffs never
14 disclosed any belief that the scope of ’044 patent was so broad until more than a
15 decade after Dr. Neal Lonky assigned the SpiraBrush product for limited use to
16 OralScan in 1998. By suing Histologics and alleging that its gynecology-specific
17 products infringe claims of the ’044 patent, Plaintiffs have made it clear that they
18 believe the patent claims cover products and methods far beyond the limited use in
19 the oral cavity originally assigned to OralScan. Such a broad interpretation opens
20 up a world of prior art that could not have been contemplated from a more limited
21 reading of the claims. If Plaintiffs are correct, *any* brush used to sample cells from
22 epithelial tissue which predates the ’044 patent could invalidate the ’044 patent.
23 Most notably is Dr. Neal Lonky’s brush, the SpiraBrush CX, that he developed,
24 marketed, and sold for more than seven years before the patent application was
25 filed.

26 It would be wholly inequitable to allow Plaintiffs’ assertion of such an
27 overly-broad scope to ensnare Histologics and others in a purported infringing
28 activity and then prevent Histologics from challenging the patent’s validity under
29 this broad-sweeping interpretation. Patent holders walk a fine line between

1 construing claims narrowly enough to remain valid and broadly enough to capture
2 infringement. Assignor estoppel would provide an unjust benefit to Plaintiffs by
3 removing one of these vital constraints. *Cf. Liebel-Flarsheim Company v. Medrad,*
4 *Inc.*, 481 F.3d 1371, 1380 (Fed. Cir. 2007) (affirming district court's conclusion
5 that all asserted claims were invalid as a result of plaintiff's broad interpretation of
6 its claims).

7
8 **6. Plaintiffs' Motion Does Not Extend To The Other**
9 **Defendants And Therefore Granting the Motion Would Not**
10 **Conserve Judicial Resources**

11 There are two other defendants, Poplar and Mattison , that also assert that the
12 '044 patent is invalid and unenforceable. Poplar and Mattison provide laboratory
13 testing services. These co-defendants are not in privity with Dr. Neal Lonky,
14 Tylon or Histologics and therefore, assignor estoppel does not apply to them. *See*
15 *Checkpoint Sys., Inc. v. All-Tag Sec. S.A.*, 315 F. Supp. 2d 660 (E.D. Penn. 2004)
16 (customer was not estopped by the doctrine of assignor estoppel from attacking
17 validity of the patent). Therefore, invalidity and unenforceability will still be at
18 issue in this case, and granting Plaintiffs' motion would not conserve judicial
19 resources or steam line the case.

20 **V. CONCLUSION**

21 For the foregoing reasons, balancing the equities tip in favor of Histologics,
22 and Histologics respectfully requests that the Court deny SMR and CDx's motion
23 to dismiss invalidity, inequitable conduct, unenforceability and fraud affirmative
24 defenses and counterclaims.
25
26
27
28

1 Dated: March 31, 2014

Respectfully submitted,
DENTONS US LLP

2
3
4 By /s/ Robert F. Kramer
Robert F. Kramer

5
6 Attorneys for Defendant and
Counterclaimant

7 HISTOLOGICS, LLC
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CERTIFICATE OF SERVICE

I, C. Gideon Korrell, hereby declare:

I am employed in the City and County of Palo Alto, California. I am over the age of eighteen years and not a party to the within action. My business address is Dentons US LLP, 1530 Page Mill Road, Palo Alto, California 94304.

On march 31, 2014, the following documents, described as:

DEFENDANT HISTOLOGICS, LLC'S MEMORANDUM OF
POINTS & AUTHORITIES IN OPPOSITION TO PLAINTIFF'S
MOTION TO DISMISS INVALIDITY, INEQUITABLE
CONDUCT, UNENFORCEABILITY AND FRAUD
AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

to be served via CM/ECF by the Clerk of the Court, upon all counsel of record registered to receive electronic filing, as indicated on the Court's website, or by United States Mail, upon those parties not registered for electronic filing.

I declare under penalty of perjury that the above is true and correct.

Executed on March 31, 2014, in Palo Alto, California.

/s/ C. Gideon Korrell

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